

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Sydney David FINKELSTEIN et al.

Confirmation No. 2727

**Application No.:** 10/008,278

Group Art Unit: 1634

Filed: November 5, 2001

Examiner: Jeanine Anne Goldberg

Title: TOPOGRAHIC GENOTYPING

Mail Stop Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE UNDER 37 C.F.R. § 1.97(c)

Sir:

The attention of the Patent and Trademark Office is hereby directed to the documents listed on the attached Form PTO-1449. A copy of each of the cited documents is attached, if required.

This Information Disclosure is being submitted after issuance of a first Office Action on the merits and after expiration of the three-month period following filing of the above-identified application, but prior to issuance of either a final Office Action or a Notice of Allowance. A check in the amount of \$180.00 is attached hereto to cover the fee set forth in 37 CFR § 1.17(p).

It is respectfully requested that the information be considered by the Examiner and that a copy of the attached Form PTO-1449 be returned indicating that such information has been considered.

In the event any further fees are required in connection with this paper, please charge Deposit Account No. 50-0573. A copy of this document is enclosed.

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Application No. 10/008,278 Attorney's Docket No. 034217-003

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Applicants' undersigned attorney may be reached by telephone at (215) 988.2700. All correspondence should be directed to the below-listed address.

Respectfully submitted,

Dated: July 22, 2005

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Tel: (215) 988.3309 Fax: (215) 988.2757 Sheet 1 of 2 U.S. Department of Commerce Form PTO-1449 DOCKET NO. 034217.0003 APPLN. NO. 10/008,278 APPLICANT: Sydney David FINKELSTEIN et al. Date Filed: July 21, 2005 **GROUP 1634** FILING DATE: 11/05/2001 U.S. PATENT DOCUMENTS Exami Document Number Date Name Class Subclass Filing Date if Initial appropriate FOREIGN PATENT DOCUMENTS Translation Document Number Date Country Class Subclass Yes/No/Abstract OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, etc.) CA Cheung Wong, et al., "Mutations in BRCA1 from Fixed, Paraffin-Embedded Tissue Can Be Artifacts of Preservation," Cancer Genet. Cytogenet. 107, pp. 21-27 (1998) A-M de Roda Husman et al., "Processing of long-stored archival cervical smears for human papillomavirus CB detection by the polymerase chain reaction," British Journal of Cancer (1995) 72, pp. 412-417  $\overline{CC}$ S. Kösel et al., "Use of neuropathological tissue for molecular genetic studies: parameters affecting DNA extraction and polymerase chain reaction," Acta Neuropathol. (1994) 88, pp. 19-25. Zhi-Ping Ren et al., "Recovering DNA and Optimizing PCR Conditions from Microdissected Formalin-Fixed and CD Paraffin-Embedded Materials," Pathobiology 2000; 68, pp. 215-217 Carla De Giorgi et al., "Formalin-induced infidelity in PCR-amplified DNA fragments," Molecular and Cellular CE Probes (1994) 8, pp. 459-462 CF Takayuki Murase, M.D., et al., "Influence of Histochemical and Immunohistochemical Stains on Polymerase Chain Reaction," The United States and Canadian Academy of Pathology, Inc., Vol. 13, No. 2, pp. 147-151 (2000) CG Florell M.D., "Preservation of RNA for Funcational Genomic Studies: a Multidisciplinary Tumor Bank Protocol," The United States and Canadian Academy of Pathology, Inc., Vol. 14, No. 2, pp. 116-128 (2001) Xavier de Lamballerie, et al., "Improved current methods for amplification of DNA from routinely processed liver CH tissue by PCR," Journal of Clinical Pathology 1994, 47, pp. 466-467 CI S.F. An, et al., "Removal of inhibitor(s) of the polymerase chain reaction from formalin fixed, paraffin wax embedded tissues," Journal of Clinical Pathology 1991, 44 pp. 924-927 P.J. Coates, et al., "Simplified procedures for applying the polymerase chain reaction to routinely fixed paraffin wax CJ sections," Journal of Clinical Pathology 1991, 44, pp. 115-118 CK Gillian Tully, et al., "Analysis of 6 VNTR loci by 'multiplex' PCR and automated fluorescent detection," Human Genetics (1993) 92, pp. 554-562 Craig R. Miller, et al., "Assessing Allelic Dropout and Genotype Reliability Using Maximum Likelihood," Genetics CL 160, (January 2002), pp. 357-366 Jonine L. Bernstein et al., "Comparison of Techniques for the Successful Detection of BRCA1 Mutations in Fixed CM Paraffin-Embedded Tissue," Cancer Epidemiology, Biomarkers and Prevention, Vol. 11, (September 2002), pp. 809-811 L.G. Dressler, et al., "Policy guidelines for the utilization of formalin-fixed, paraffin-embedded tissue sections: the CN UNC SPORE experience," Breast Cancer Research and Treatment 58, pp. 31-39 (1999) M.P. Burton, et al., "Comparison of Histologic Stains for Use in PCR Analysis of Microdissected, Paraffin-CO Embedded Tissues," BioTechniques, Vol. 24, No. 1, pp. 86-91 (1998) CP Cecilia Williams, et al., "A High Frequency of Sequence Alterations is Due to Formalin Fixation of Archival Specimens," American Journal of Pathology, Vol. 155, No. 5, (November 1999), pp. 1467-1471 John W. Gillespie, et al., "Evaluation of Non-Formalin Tissue Fixation for Molecular Profiling Studies," American CQ Journal of Pathology, Vol. 160, No. 2, (February 2002), pp. 449-457 CR Susan E. Goelz, et al., "Purification of DNA from Formaldehyde Fixed and Paraffin Embedded Human Tissue," Biochemical and Bio Physical Research Communications," Vol. 130, No. 1, 1985, pp. 118-126 CS Beverly Barton Rogers, et al., "Analysis of DNA in Fresh and Fixed Tissue by the Polymerase Chain Reaction," American Journal of Pathology, Vol, 136, No. 3, March 1990, pp. 541-548 CT Kevin F. Forsthoefel, M.D., et al., "Optimization of DNA Extraction from Formalin-Fixed Tissue and Its Clinical Application in Duchenne Muscular Dystrophy," Anatomic Pathology, A.J.C.P, July 1992, pp. 98-104

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U.S. Department of Commerce Date Filed: July 21, 24, 24, 24, 24, 24, 24, 24, 24, 24, 24		APPLICANT: Sydney David FINKELSTEIN et al.	
Date I'll	cu. <u>July 21<del>, 200</del>0</u>	FILING DATE: 11/05/2001	GROUP 1634

CU	James M. Rae, et al., "Genotyping for polymorphic druge metabolizing enzymes from paraffin-embedded and immunohistochemically stained tumor samples," Pharmacogenetics 2003, Vol. 13, No. 8, pp. 501-507		
CV	Jos C.F. M. Dreesen, et al., "Allelic Dropout Caused by Allele-Specific Amplification Failure in Single-Cell PCR of the Cystic Fibrosis ΔF508 Delection," Journal of Assisted Reproduction and Genetics, Vol. 13, No. 2, 1996, pp. 112-114		
CW	P. Wiegand, et al., "DNA degradation in formalin fixed tissues," Pathologe, 1996 Nov; 17(6); 451-7 (abstract only)		
Examiner S	Signature:	Date Considered:	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s). PTO-1449.doc